Louisiana Office of Public Health Laboratories	
Test Name	SERODIA® - TP-PA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86780
Synonyms	TP-PA, *Treponema pallidum particle agglutination*, Syphilis, *Treponema pallidum*
Brief Description of Test	Serodia® TP-PA is a qualitative gelatin article agglutination assay intended to be used for the detection of *Treponema pallidum* antibodies in human serum as an aid in the diagnosis of syphilis. The TP-PA is a reflex test that is performed when the Syphilis EIA is initially reactive and the VDRL is non-reactive.
Possible Results	Nonreactive Inconclusive Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	1 mL serum
Collection Instructions	Blood should be collected in a plastic, sterile STD Program approved collection tube. Please follow the manufacturer's instructions on clot time requirements and centrifuge speed/ time requirements. Label specimen with Patient Name and a 2nd Unique Identifier such as a chart number or medical record number. DOB is not considered unique. Complete a STD/HIV Lab Form for each specimen or order test in StarLIMS. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date and time of collection, specimen source, test requested, submitter's name, address, fax and contact number. Additional information regarding patients' address is requested. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.

Storage and Transport Instructions	Specimens must be shipped refrigerated (2-8°C) and can be stored for up to 5 days. For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If a specimen is frozen, indicate the Date/Time specimen was frozen on the lab form or the LIMS manifest. Serum may be frozen and thawed only once.
Causes for Rejection	Improper labeling, expired collection tubes , unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), specimen age >5 days if specimen has not been frozen at -20°C or colder. Improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	The Serodia® TP-PA test is specific for detecting *Treponema pallidum* antibodies in serum. It does not detect *T. pallidum* directly. As will all serological tests for syphilis, interpretation of results obtained with this test must be used in conjunction with the patient's clinical symptoms, medical history and other clinical and/or laboratory findings to produce an overall clinical diagnosis. All treponemal tests tend to remain rective following treponemal infection; therefore, they should not be used to evaluate response to therapy. This test may be reactive in a small percentage (less than 1%) of normal or healthy persons; these flase-positive results are often transient, their cause unknown. False positive results may occur in association with other underlying illnesses and may be reactive in persons from areas where yaws or pinta was, or is, endemic. Samples from patients with HIV, Leprosy, Toxoplasmosis, H. pylori, or drug addiction may react, on occasion, with either the sensitized or the unsensitized particles, causing false-positive or Inconclusive results.
Interfering Substances	Specimens containing erythrocytes or other visible matter should be centrifuged prior to testing to prevent interference with test results.
References	Serodia® - TP-PA Package Insert Captia™ Syphilis IgG EIA Package Insert BD VDRL Antigen Package Insert
Additional Information	This is a reflex test that is automatically ordered on a sample when Captia™ Syphilis IgG EIA assay is equivocal or reactive and the VDRL assay is non reactive.
Release Date	03/15/2016
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	